

Tba

510(k) SUMMARY
Ion Beam Applications S.A.

19 July 2010

K101508

Applicant

Ion Beam Applications S.A.
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AUG 06 2010

Contact and Agent for Ion Beam Applications S.A.

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Iba

Classification Name

Medical charged-particle radiation therapy systems. (21 C.F.R. §892.5050)

Predicate Device

The PTS (proton therapy system) is substantially equivalent to the previously cleared IBA proton therapy system (K983024). The current PTS and its predicate device have the same intended use and principles of operation, and are substantially equivalent in terms of performance and technological characteristics.

Like its predicate IBA PTS device, this modified PTS is a device designed to produce and deliver a proton beam for treatment of a patient. Also like its predicate device, it is intended for use in the therapeutic application of a proton beam for the treatment of localized tumors or other diseases that are susceptible to treatment by radiation.

The predicate device also provides the same or substantially equivalent functions, characteristics, and accessories as does the currently modified PTS. All these devices are comprised of beam production equipment which generates the beam used by the beam delivery systems.

The technological aspects of a patient treatment consist of protons generated by the beam production equipment, directed to the patient's treatment site by the beam delivery system. The patient is put into the correct position relative to the beam by a positioning system.

Indication for Use

The PTS is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation.

Description of the device modifications

The scope of this change to the proton therapy system is an interface to an external medical device. This external medical device provides a signal upon which the PTS starts or stops the beam during treatment. This external medical device is not part of the proton therapy system. The new interface as part of the PTS is called universal beam triggering interface (UBTI).

The adequate performance and safety test results have been provided to the FDA in the submission. The conclusions drawn from those tests demonstrate that the device is as safe, as effective, and performs as well as the already legally marketed device.

Technological Characteristics

The device is designed to: (1) create and deliver the proton beam to the patient treatment location; (2) produce a transverse and longitudinal dose distribution appropriate for the patient's treatment; and (3) deliver the designated dose to the patient's treatment site. The PTS has two primary components: (1) the beam

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delivery equipment, which directs the proton beam to the patient's treatment site within the patient treatment location and ensures the patient critical functions are properly and safely accomplished; and (2) the beam production equipment, which includes a cyclotron and delivery system to produce the proton beam and deliver it to the patient treatment locations. In addition to these primary components, the PTS includes a Therapy Safety System to protect against unsafe conditions, having both automatic and manual controls to shut down the PTS in the event problems occur; and a computer-based Therapy Control System which controls the parameters of the proton beam.

Following the successive changes to the original 510(k) submission, several features have been already added:

- (1) PPVS (K053641): The Patient positioning verification system (PPVS) is interfaced to a Treatment Planning System (TPS) or an Oncology Information System (OIS) for downloading the treatment plan and the associated Digitally Reconstructed Radiographs (DRR) from the TPS in DICOM format;
- (2) SIS and US (K060695): addition of 2 treatment modes. The Single Scattering (SIS) technique is dedicated to the irradiation of fields smaller than seven centimetres, the Uniform Scanning (US) technique is an active technique for spreading beam in a transversal direction to large irradiation fields;
- (3) IOIS (K061913) - An automatic network-based interface between an Oncology Information System (OIS) to the PTS for the input of patient information, which information initially is entered into the OIS by means of a Graphical User Interface has been added.
- (4) Pencil Beam Scanning (K082416) - The pencil beam scanning is defined as the act of moving a charged particle beam of particular properties and/or changing one or more of the properties of that beam (e.g. Intensity, size, position, etc.). The goal of this beam delivery is to deliver the appropriate proton fluence according to a prescription. This prescription provides a map of the fluence that is necessary to deliver at each location on the target. Thus the beam is moved to each location on the target and the appropriate fluence is deposited at each location.
- (4) Robotic PPS (K083058) – The PTS includes new PPS. It is a SCARA-type arm robot. The X- and Y-translations from the current PPS have been replaced by two rotations around vertical axes. The vertical motion (Z-axis) from the current PPS remains a translation in the Robot PPS.
- (5) Proteus RTT and patient gantry access upgrade (K091629) – The Proteus RTT and patient gantry access upgrade consists of a redesign of the gantry patient enclosure (PE) and an associated technology update of the PTS interlock controller.
- (6) Inclined beam line (K092796) – The proton therapy system can be equipped with an inclined beam line enabling the beam delivery device to be positioned at two angles: 30° and 90°.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

ION Beam Applications S.A.
% Mr. John B. Reiss
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PHILADELPHIA PA 19102

NOV 17 2011

Re: K101508

Trade/Device Name: IBA Proton Therapy System – Proteus 235
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: LHN
Dated: July 23, 2010
Received: July 26, 2010

Dear Mr. Reiss:

This letter corrects our substantially equivalent letter of August 6, 2010.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely Yours,



Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indications for Use Form

510(k) Number (if known): k101508

Device Name: IBA PROTON THERAPY SYSTEM – PROTEUS 235

AUG 06 2010

Indications for Use:

« The Proton Therapy System – Proteus 235 is a medical device designed to produce and deliver a proton beam for the treatment of patients with localized tumors and other conditions susceptible to treatment by radiation. »

Prescription Use _____
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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